§ 803.32 If I am a user facility, what information must I submit in my individual adverse event reports?

You must include the following information in your report, if reasonably known to you, as described in § 803.30(b). These types of information correspond generally to the elements of FDA Form 3500A:

(a) Patient information (Form 3500A, Block A). You must submit the following:
   (1) Patient name or other identifier;
   (2) Patient age at the time of event, or date of birth;
   (3) Patient gender; and
   (4) Patient weight.

(b) Adverse event or product problem (Form 3500A, Block B). You must submit the following:
   (1) Identification of adverse event or product problem;
   (2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:
      (i) Life-threatening injury or illness;
      (ii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
      (iii) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;
   (3) Date of event;
   (4) Date of report by the initial reporter;
   (5) Description of event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;
   (6) Description of relevant tests, including dates and laboratory data; and
   (7) Description of other relevant history, including preexisting medical conditions.

(c) Device information (Form 3500A, Block D). You must submit the following:
   (1) Brand name;
   (2) Type of device;
   (3) Manufacturer name and address;
   (4) Operator of the device (health professional, patient, lay user, other);
   (5) Expiration date;
   (6) Model number, catalog number, serial number, lot number, or other identifying number;
   (7) Date of device implantation (month, day, year);
   (8) Date of device explantation (month, day, year);
   (9) Whether the device was available for evaluation and whether the device was returned to the manufacturer; if so, the date it was returned to the manufacturer; and
   (10) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)

(d) Initial reporter information (Form 3500A, Block E). You must submit the following:
   (1) Name, address, and telephone number of the reporter who initially provided information to you, or to the manufacturer or distributor;
   (2) Whether the initial reporter is a health professional;
   (3) Occupation; and
   (4) Whether the initial reporter also sent a copy of the report to us, if known.

(e) User facility information (Form 3500A, Block F). You must submit the following:
   (1) An indication that this is a user facility report (by marking the user facility box on the form);
   (2) Your user facility number;
   (3) Your address;
   (4) Your contact person;
   (5) Your contact person’s telephone number;
   (6) Date that you became aware of the event (month, day, year);
§ 803.40 If I am an importer, what kinds of individual adverse event reports must I submit, when must I submit them, and to whom must I submit them?

(a) Reports of deaths or serious injuries. You must submit a report to us, and a copy of this report to the manufacturer, as soon as practicable but no later than 30 calendar days after the day that you receive or otherwise become aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of your marketed devices may have caused or contributed to a death or serious injury. This report must contain the information required by §803.42, on FDA form 3500A or an electronic equivalent approved under §803.14.

(b) Reports of malfunctions. You must submit a report to the manufacturer as soon as practicable but no later than 30 calendar days after the day that you receive or otherwise become aware of information from any source, including user facilities, individuals, or through your own research, testing, evaluation, servicing, or maintenance of one of your devices, that reasonably suggests